

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF TEXAS  
TYLER DIVISION**

**MALCOLM WYDERMYER**

v.

**JANSSEN PHARMACEUTICALS,  
INC., et al.**

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**CASE NO. 6:16-CV-1000**

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**ORDER ADOPTING REPORT AND RECOMMENDATION  
OF THE UNITED STATES MAGISTRATE JUDGE**

The Report and Recommendation of the Magistrate Judge, which contains her findings, conclusions, and recommendation for the disposition of this matter, has been presented for consideration. The Report and Recommendation recommends that Defendant Zydus Pharmaceuticals, Inc.'s Motion to Dismiss (Docket No. 55) and Defendant Par Pharmaceutical Companies, Inc.'s Motion to Dismiss (Docket No. 60) be **GRANTED-IN-PART** and **DENIED-IN-PART**. The Report and Recommendation recommends that the motions to dismiss be denied to the extent that Defendants seek dismissal of Plaintiff's claims as meritless, preempted by the FDA, barred by the learned intermediary doctrine and barred by the statute of limitations. Docket No. 75. The Report and Recommendation recommends granting the motion to dismiss the complaint as not sufficiently pled, with leave to amend. *Id.* Plaintiff and Defendant Par Pharmaceutical Companies, Inc. ("Par") filed written objections to the Report and Recommendation on August 2, 2017. Docket Nos. 76, 77.

In its written objections, Par re-asserts the same arguments that were raised in its motion to dismiss and in its reply brief regarding whether Plaintiff's negligent and fraudulent off-label promotion claim is preempted under federal law and whether Plaintiff's claim is barred by Texas's learned intermediary doctrine. Docket No. 77. These arguments were fully considered and analyzed in the Report and Recommendation. Docket No. 75. The Fifth Circuit, despite broadly applying *Mensing* preemption,<sup>1</sup> has not foreclosed claims for wrongful off-label promotion. *Rusk v. Wyeth-Ayerherst Labs., Inc.*, 2015 WL 3651434, at \*4 (W.D. Tex. June 11, 2015) (*report and recommendation adopted*, 2015 WL 11050913 (W.D.Tex. Oct. 26, 2015)). Furthermore, taking Plaintiff's allegations in the complaint as true, Plaintiff is alleging that Defendants negligently and/or fraudulently promoted their drug off-label. Docket No. 2. He is not asserting a claim for failure to warn, and the learned intermediary doctrine does not apply.

Par additionally argues that Plaintiff has not shown that he was of unsound mind sufficient to toll the statute of limitations. Docket No. 77. At the motion to dismiss stage of the proceedings, the Court accepts all well-pleaded facts as true and views them in the light most favorable to the plaintiff. *Bustos v. Martini Club*, 599 F.3d 458, 461 (5th Cir. 2000). Here, Plaintiff's mental health disability is sufficiently pled in the Fifth Amended Complaint to survive a motion to dismiss.

Finally, Plaintiff contends that he sufficiently pled a claim of negligent off-label promotion. As stated above, the Fifth Circuit left open the possibility of bringing a claim for negligent or fraudulent off-label promotion. *Rusk*, 2015 WL 3651434, at \*6 (citing *Whitener*, 2015 WL 1570051 at \*16). Plaintiff asserts that the Report and Recommendation is not clear as to whether the Court is applying the pleading standard in Federal Rules of Civil Procedure ("Rule") 8(a) for

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<sup>1</sup> *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 612 n.2 (U.S. 2011).

a negligence claim or Rule 9(b) for a fraud claim. Docket No. 76. Indeed, Plaintiff's Fifth Amended Complaint is not clear about whether Plaintiff is asserting a claim for negligence or fraud. The pleading asserts that Defendants Zydus and Par "negligently and/or fraudulently instructed its sales representatives during all relevant times to market and promote risperidone as safe and effective to mental health facilities, organizations, and medical professionals for off-label uses." Docket No. 44 at 19.

As written, the pleading alleges negligence or fraud. The allegations in the Fifth Amended Complaint are not sufficient to meet the Rule 9(b) standard of particularity for circumstances amounting to fraud. As described in the Report and Recommendation (Docket No. 75), the pleading should explain the promotional activities taken by agents or representatives of Defendants to influence specific physicians involved in Plaintiff's treatment to prescribe risperidone off-label and/or the actions taken by Defendants' agents or representatives to conceal from Plaintiff's physicians the risks associated with the off-label use of risperidone. *Rusk*, 2015 WL 3651434, at \*6. Similarly, the pleading is not clear as to whether Plaintiff is asserting negligence, fraud or both. A statement that Plaintiff alleges that Defendants acted negligently and/or fraudulently does not sufficiently put Defendants on notice of a claim showing that the pleader is entitled to relief. Rule 8(a). For these reasons, the pleading does not sufficiently plead this claim.

Leave should be freely given to amend the complaint, especially where amendment would not be futile. Rule 15(a)(2). Par objects to granting Plaintiff leave to amend the claim, but Par has not shown that amendment would be futile. Docket No. 77.

Having made a *de novo* review of the written objections filed by Plaintiff and Defendant in response to the Report and Recommendation, the Court concludes that the findings and conclusions of the Magistrate Judge are correct and the objections are without merit. It is therefore

**ORDERED** that the Report and Recommendation filed on July 19, 2017 is **ADOPTED**.

Defendants' Motions to Dismiss (Docket Nos. 55, 60) are **GRANTED-IN-PART** and **DENIED-IN-PART**. The motions are **GRANTED** to the extent that Plaintiff has not sufficiently pled a claim for negligent or fraudulent off-label promotion. The motions are **DENIED** in all other respects. Plaintiff shall file an amended complaint curing the deficiencies identified in the Report and Recommendation and in this Order within **twenty (20) days**.

**SIGNED** this 19th day of September, 2017.

*Robert W. Schroeder III*  
ROBERT W. SCHROEDER III  
UNITED STATES DISTRICT JUDGE